4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0510]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Substances Prohibited from Use in Animal Food or Feed

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0627. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd.; COLE-14526, Silver Spring, MD 20993-0002 PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Substances Prohibited From Use in Animal Food or Feed--21 CFR Part 589 (OMB Control Number 0910-0627--Revision)

This regulation prohibits the use of certain cattle origin materials in the food or feed of all animals to help prevent the spread of bovine spongiform encephalopathy (BSE) in U.S. cattle. BSE is a progressive and fatal neurological disorder of cattle that results from an unconventional transmissible agent. BSE belongs to the family of diseases known as transmissible spongiform encephalopathies (TSEs). All TSEs affect the central nervous system of infected animals. These measures will further strengthen existing safeguards against BSE.

In the Federal Register of November 21, 2014 (79 FR 69493), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received however it did not respond to any of the four information collection topics solicited and is therefore not addressed by the Agency.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Recordkeeping Burden[1]

21 CFR Section 589.2001; Substances Prohibited from Use in Animal Food or Feed	No. of Record-keepers	No. of Records per Record-keeper	Total Annual Records	Average. Burden per Record-keeper	Total Hours	Operating and Maintenance Costs
589.2001(c)(2)(vi) and (c)(3)(i)	175	1	175	20	3,500	$59,500
589.2001 (c)(2)(ii)	50	1	50	20	1,000	$17,000
589.2001(c) (3)(i)(A)	175	1	175	26	4,550	$80,580

TOTAL					9,050	$157,080

[1] There are no capital costs associated with this collection of information.

Description of Respondents for Recordkeeping: Rendering facilities, medicated feed manufacturers, livestock feeders.

The Agency's recordkeeping burden estimate was calculated by multiplying the number of recordkeepers times the number of records per recordkeeper to determine the total annual number of records. The total number of annual records were then multiplied by the average burden per recordkeeper to determine the total number of burden hours.

Table 2.--Estimated Annual Reporting Burden[1]

21 CFR Section 589.2001(f)	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average. Burden per Respondent	Total Hours
One-time (initial) burden	1	1	1	80	80
Burden from future review	1	1	1	26	26

[1]There are no capital costs or operating costs associated with the collection of information.

Description of Respondents for Reporting: The final regulation on BSE (73 FR 22720) included a provision that exempts cattle materials prohibited in animal feed (CMPAF) from designated countries from the prohibition on its use in animal feed. A foreign country seeking this designation will submit a written request to FDA that includes a variety of information about the country's BSE status (§589.2001(f)). During the past 6 years, FDA received 2 requests from countries to be exempted from CMPAF restrictions.

One-Time (initial) Reporting Burden

There is a one-time burden to countries that apply to FDA seeking to be designated as not subject to restrictions applicable to CMPAF. We estimate that each country that applies for an exclusion will spend 80 hours putting information together to submit to FDA. Table 2 row 1 presents the one-time burden for the exclusion. (See final BSE regulation at 73 FR 22754).

Recurring Burden

Countries that successfully petition FDA to be designated as exempt from certain BSE-related restrictions applicable to animal feed will be subject to future review by FDA to ensure that their designation remains appropriate. As part of this process, FDA may ask designated countries from time-to-time to confirm that their BSE situation and the information submitted by them in support of their original application remains unchanged. We assume it will take FDA and the designated country undergoing a review in the future about one third the time and effort it did when the information was submitted. Table 2 row 2 presents the expected recurring burden.

Dated: March 2, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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